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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/898,616	07/02/2001	Aprile L. Pilon	116142/00170	3118
31013	7590	12/30/2004	EXAMINER	
KRAMER LEVIN NAFTALIS & FRANKEL LLP INTELLECTUAL PROPERTY DEPARTMENT 919 THIRD AVENUE NEW YORK, NY 10022			HUNNICUTT, RACHEL KAPUST	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 12/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/898,616

Applicant(s)

PILON ET AL.

Examiner

Rachel K. Hunnicutt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-100 is/are pending in the application.
- 4a) Of the above claim(s) 1-34, 56-73 and 79-100 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-55 and 74-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

RESPONSE TO AMENDMENT

Applicant's amendment filed September 27, 2004 is acknowledged. Claims 36, 43, 46, 49, 50, 52, 53, 55, and 74 are amended. Claims 35-55 and 74-78 are pending and under consideration. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim Rejections/Objections Withdrawn

The objection to the specification regarding the phrase "Seq. ID. Nos." is withdrawn in response to Applicants' amendment to the specification.

The objection to the specification regarding the brief description of Figure 5 is withdrawn in response to Applicants' amendment to the specification.

The objection to the specification regarding the use of trademarks is withdrawn in response to Applicants' amendment to the specification.

The objection to claims 53 and 54 is withdrawn in response to Applicants' amendments to the claims.

The rejection of claim 52 under 35 U.S.C. 112, second paragraph, for insufficient antecedent basis, is withdrawn in response to Applicants' amendment to the claim.

The rejection of claims 43 and 46 under 35 U.S.C. 112, second paragraph, regarding the use of trademarks in claims, is withdrawn in response to Applicants' amendments to the claims.

The rejection of claims 74-78 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, is withdrawn in response to Applicants' amendments to the claims.

The rejection of claim 49 under 35 U.S.C. 103(a) as being unpatentable over Torkkeli *et al.* in view of Andersson *et al.* and Mourot *et al.* is withdrawn in response to Applicants' arguments on p. 11-12 of the response.

Claim Rejections Maintained/New Grounds of Rejection

Claim Rejections - 35 USC § 112

Claims 36 and 50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 36 and 50 recite the limitation "synthetic gene" in reference to claims 35 and 49, respectively. There is insufficient antecedent basis for this limitation in the claim. Claims 35 and 49 do not refer to a synthetic gene. This rejection may be obviated by either amending claims 35 and 49 so that they refer to a bacterial cell expressing a synthetic gene encoding rhUG or by amending claims 36 and 50 so that they read "wherein the rhUG expressed in the bacterial cells".

The rejection of claims 36 and 50 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is maintained for reasons of record on p. 4 of paper no. 0104. As amended, it appears that claims 36 and 50 are meant to be drawn to Markush groups, wherein the synthetic gene comprises at least one of a group consisting of SEQ ID NO: 1, 2, 3 or 4. If Applicants intend to have the claims encompass genes comprising SEQ ID NO: 1, 2, 3, or 4, the claims should be amended so that they contain proper Markush groups. If, however, Applicants meant that the gene should comprise SEQ ID NOS: 1, 2, 3, and 4, the claims should be amended to read "wherein the synthetic gene expressed in the bacterial cells comprises SEQ ID NOS: 1, 2, 3, and 4.

Claims 42 and 52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 42 and 52 refer to "Macro Q" anion exchange columns. It

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appears that Applicants are referring to Bio-Rad's MACRO-PREP™ High Q anion exchange columns, which is a trademarked product. Thus, the claim scope is uncertain since a trademark cannot be used properly to identify any particular product. MPEP 2173.05(u). Applicants need to amend the claims so that they refer to the generic properties of the column thus clarifying the scope of the claims.

Claims 74-78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In step (c) of claim 74, Applicants refer to "analyzing the process intermediates to determine purity relative to purified recombinant human uteroglobin taken from *the preceding step or steps of the process of claim 35*" (emphasis added). It is not clear what applicants are referring to when they say "the preceding step or steps of the process of claim 35." Do they mean the preceding step in claim 74, which is analyzing the process intermediates to determine purity relative to unpurified recombinant human uteroglobin? If so, the reference would be improper because purified recombinant human uteroglobin was not taken in this step. Do Applicants mean the purified human uteroglobin that is recovered in step (i) of claim 35? If so, Applicants should refer to such. Applicants must clarify which step or steps they are referring to.

Claim Rejections - 35 USC § 103

The rejection of claim 55 under 35 U.S.C. 103(a) as being unpatentable over Andersson et al. in view of U.S. Patent No. 4,691,009 and Shin et al. is maintained for reasons of record on p. 7 of paper no. 0104.

Applicants argue that the sequence of gel filtration and ion exchange steps in Andersson differs substantially from applicants' methods (p. 11 of response).

Applicants' arguments have been fully considered but have not been found to be persuasive. Claim 55 simply refers to the use of at least one filtration step and at least one exchange column, which Andersson et al. teach. Claim 55 does not refer to any sequence of steps, thus Applicants' arguments are not relevant to claim 55.

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Double Patenting

The rejection of claims 35-55 and 74-78 under 35 U.S.C. 101, as being provisionally rejected for claiming the same invention as that of claims 35-41, 48-61, and 80-84 of copending Application No. 10/187498 is maintained for reasons of record on p. 8 of paper no. 0104.

Conclusion

NO CLAIMS ARE ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel K. Hunnicutt whose telephone number is (571) 272-0886. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RKH
12/28/04


JANET ANDRES
PRIMARY EXAMINER